

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Sanjay K. Nigam et al.

Art Unit: 1652

Serial No.: 10/608,783

Examiner: Unknown

Filed : June 27, 2003

Title

: METHODS OF TISSUE REPAIR AND REGENERATION AND TISSUE

्यतीत्र-

ENGINEERED COMPOSITIONS

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE

Dear Sir:

Applicants call attention to the attached Information Disclosure Statement and documents listed on form PTO-1449.

This filing is being made before the receipt of a first Office action on the merits. No fee is required.

The documents are in the English language; hence no concise explanation is necessary per Rule 98(a)(3).

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Scott C. Harris

Respectfully submitted,

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			Sheet 1 of 7
(Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 15670-053001	Application No. 10/608,783
MAR 1.5 2004 Differention Discl	isclosure Statement Applicant	Applicant Sanjay K. Nigam et al.	
by Apr (Use several she	ets if necessary)	Filing Date June 27, 2003	Group Art Unit Unknown

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA						
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	Foreign Patent Documents or Published Foreign Patent Applications							
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	AL							
	AM							
	AN							
	AO							
	AP							

	Other Documents (include Author, Title, Date, and Place of Publication)				
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		Milner, et al., "A Novel 17 kD Heparin-Binding Growth Factor (HBGF-8) in Bovine Uterus:			
	AQ	Purification and N-Terminal Amino Acid Sequence", Biochemical and Biophysical Research			
		Communications, Vp;/ 165, No. 3, pp. 1096-1103, December 29, 1989			
	AR	Mitsiadis, et al., "Expression of the heparin-binding cytokines, midkine (MK) and HB-GAM (pleiotrophin) is associated with epithelial-mesenchymal interactions during fetal development and organogenesis", Development, Vol. 121, pp. 37-51, 1995			
	AS	Sato, et al., "Pleiotrophin as a Swiss 3T3 Cell-Derived Potent Mitogen for Adult Rat Hepatocytes", Experimental Cell Research, Vol. 246, Number 1, pp. 152-164, January 10, 1999			

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Substitute Form PTO-1449 (Modified)	•		Application No. 10/608,783	
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	Other D	ocuments (include Author, Title, Date, and Place of Publication)
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Initial	ID	Document Policy of Million of Million in Name 1 Policy of Million in Name 2 Policy of
	AT	Kurtz, et al., "Pleiotrophin and Midkine in Normal Development and Tumor Biology", <u>Critical</u> Reviews in Oncogenesis, Vol. 6, No. 2, pp. 151-177, 1995
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	AU	pathways of developing axonal processes in vivo and neurite outgrowth in vitro induced by HB-
		GAM" <u>Developmental Brain Research</u> , Voll. 79, pp. 157-176, 1994
		Imai, et al., "Osteoblast Recruitment and Bone Formation Enhanced by Cell Matrix-associated
	AV	Heparin-binding Growth-associated Molecule (HB-GAM), The Journal of Cell Biology, Vol. 143,
		Number 4, pp. 1113-1128, November 16, 1998
	AW	Tomita, et al, "Direct in Vivo Gene Introduction into Rat Kidney", Biochemical and Biophysical
	AW	Research Communications, Vol. 186, No. 1, pp. 129-134, July 15, 1992
	AX	Zhu, et al., "Systemic Gene Expression After Intravenous DNA Delivery into Adult Mice", Science,
		Vol. 261, pp. 209-211, July 9, 1993
	AY	Moullier, et al., "Adenoviral-mediated gene transfer to renal tubular cells in vivo", Kidney
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	AZ	Montesano, et al., "Induction of Epithelial tubular Morphogenesis in Vitro by Fibroblast-Derived
		Soluble Factors", Cell, Vol. 66, pp. 697-711, August 23, 1991
	AAA	Bladt, et al., "Essential role for the c-met receptor in themigration of myogenic precursor cells into
-		the limb bud", Nature, Vol. 376, No. 6543, pp. 68-771, August 31, 1995
	ABB	Schmidt, et al., "Scatter factor/hepatocyte growth factor is essential for liver development", Nature,
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	ACC	Schuchardt, et al., "Renal agenesis and hypodysplasia in ret-k- mutant mice result from defects in
		ureteric bud development", Development, Vol. 122, No. 6, pp. 1919-1929, June, 1996
	ADD	Metzger, et al., "Genetic Control of Branching Morphogenesis", Science, Vol. 284, pp. 1635-1639, June 4, 1999
		Ohuchi, et al., "FGF10 Acts as a Major Ligand for FGF Receptor 2 IIIb in Mouse Multi-Organ
	AEE	Development", Biochemical and Biophysical Research Communications, Vol. 277, No. 3, pp. 643-
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		Bullock, et al., "Renal agenesis in mice homozygous for a gene trap mutation in the gene encoding
	AFF	heparan sulfate 2-sulfotransferase", Genes & Development, Vol. 12, No. 12, pp. 1894-1906, June
		15, 1998
	AGG	Bullock, et al., "Developmental and species differences in the response of the ureter to metabolic
		inhibition", European Journal of Physiology, Vol. 436, No. 3, pp. 443-448, August, 1998
		Davies, et al., "Sulphated proteoglycan is required for collecting duct growth and branching but not
	AHH	nephron formation during kidney development", <u>Development</u> , Vol. 121, Issue 5, pp. 1507-1517,
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	AII	Kispert, et al., "Proteoglycans are required for maintenance of Wnt-11 expression in the ureter tips"
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	AJJ	Montesano, et al., "Identification of a Fibroblast-Derived Epithelial Morphogen as Hepatocyte
		Growth Factor", Cell, Vol. 67, No. 5, pp. 901-908, November 29, 1991
	AKK	Zelzer, et al., "Cell fate choices in <i>Drosophila</i> tracheal morphogenesis", <u>BioEssays</u> , Vol. 22, No. 3,
		pp. 219-226, March, 2000
	ALL	Enomoto, et al., "GFRα-1 Deficient Mice Have Deficits in the Enteric Nervous System and Kidneys", Neuron, Vol. 21, No. 2, pp. 317-324, August, 1998
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	ANN	Imai, et al., "Gene transfer and kidney disease", <u>Journal of Nephrology</u> , Vol. 11, No. 1, pp. 16-19, January-February, 1998
	AOO	Imai, et al., "Strategies of gene transfer fo the kidney", <u>Kidney</u> , Vol. 53, No. 2, pp. 264-272, February, 1998
	APP	Meng, et al., "Pleiotrophin signals increased tyrosine phosphorylation of $\beta$ -catenin through inactivation of the intrinsic catalytic activity of the receptor-type protein tyrosine phosphatase $\beta/\zeta$ ", Proc. Natl. Acad. Sci., Vol. 97, No. 6, pp. 2603-2608, March 14, 2000
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	ARR	Vainio, et al., "Syndecan and Tenascin Expression is Induced by Epithelial-Mesenchymal Interactions in Embryonic Tooth Mesenchyme", <u>The Journal of Cell Biology</u> , Vol. 108, No. 5, pp. 1945-1954, May, 1989
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	ATT	Thadhani, et al., "Acute renal failure", <u>The New England Journal of Medicine</u> , Vol. 334, No. 2, pp. 1448-1460, May 30, 1996
	AUU	Bonventre, et al., "Acture renal failure. I. Relative importance of proximal vs. distal tubular injury", Am. J. Physiol, Vol. 275, No. 5, pp. F623-F631, November, 1998
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	AWW	Fish, et al., "Alterations of Epithelial Polarity and the Pathogenesis of Disease States", <u>The New England Journal of Medicine</u> , Vol. 330, No. 14, pp. 1580-1588, April 7, 1994
	AXX	Tsukamoto, et al., "Tight Junction Proteins Form Large Complexes and Associate with the Cytoskeleton in an ATP D epletion Model for Reversible Junction Assembly", The Journal of Biological Chemistry, Vol. 272, No. 26, pp. 16133-16139, June 27, 1997
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	AZZ	Gailit, et al., "Redistribution and dysfunction of integrins in cultured renal epithelial cells exposed to oxidative stress", American Journal of Physiology, Vol. 264, No. 1, pp. F149-F157, January, 1993
	AAAA	Lieberthal, et al., "β Integrin-Mediated Adhesion between Renal Tubular Cells after Anoxic Injury", Journal of the American Society of Nephrology, Vol. 8, Issue 2, pp. 175-183, February, 1997
	ABBB	Zuk, et al., "Polarity, integrin, and extracellular matrix dynamics in the postischemic rat kidney", American Journal of Physiology, Vol. 275, No. 3, pp. C711-C731, September, 1998
	ACCC	Gumbiner, et al., "The Role of the Cell Adhesion Molecule Uvomorulin in the Formation and Maintenance of the Epithelial Junctional Complex", The Journal of Cell Biology, Vol. 107, No. 4, pp. 1575-1587, October, 1988
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	AEEE	Mandel, et al., "ATP depletion: a novel method to study junctional properties in epithelial tissues. II. Internalization of Na <sup>+</sup> , K <sup>+</sup> -ATPase and E-cadherin", <u>Journal of Cell Science</u> , Vol. 107, Part 12, pp. 309-316, December, 1994
	AFFF	Tsukita, et al., "Structural and signalling molecules come together at tight junctions", <u>Current Opinion in Cell Biology</u> , Vol. 11, No. 5, pp. 628-633, October, 1999
	AGGG	Denker, et al., "Molecular structure and assembly of the tight junction", <u>American Journal of Physiology</u> , Vol. 274, No. 1, pp. F1-F9, January, 1998
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	AIII	Kuznetsov, et al., "Folding of Secretory and Membrane Proteins", <u>The New England Journal of Medicine</u> , Vol. 339, No. 23, pp. 1688-1695, December 3, 1998
	AJJJ	Van Why, et al., "Thresholds for cellular disruption and activation of the stress response in renal epithelia", American Journal of Physiology, Vol. 277, No. 2, pp. F227-F234, August, 1999
	AKKK	Gething, et al., "Protein folding in the cell", Nature, Vol. 355, No. 6355, pp. 33-45, January, 1992
	ALLL	Gabai, et al., "Rise in heat-shock protein level confers tolerance to energy deprivation", <u>FEBS</u> <u>Letters</u> , Vol. 327, No. 3, pp. 247-250, August, 1993
	AMMM	Georgopoulos, et al., "Role of the major heat shock proteins as molecular chaperones", <u>Annual Review of Cell Biology</u> , Vol. 9, pp. 601-634, 1993
	ANNN	Yoo, et al., "Anti-Inflammatory Effect of Heat Shock Protein Induction is Related to Stabilization of IκBα Through Preventing IκB Kinase Activation in Respiratory Epithelial Cells", <u>The Journal of Immunology</u> , Vol. 164, No. 10, pp. 5416-5423, May 15, 2000
	A000	Rauchman, et al., "An osmotically tolerant inner medullary collecting duct cell line from an SV40 transgenic mouse", <u>American Journal of Physiology</u> , Vol. 265, No. 3, pp. F416-F424, September, 1993
	APPP	Barasch, et al., "A ureteric bud cell line induces nephrogenesis in two steps by two distinct signals", American Journal of Physiology, Vol. 271, No. 1, pp. F50-F61, July, 1996
	AQQQ	Barasch, et al., "Ureteric bud cells secrete multiple factors, including bFGF, which rescue renal progenitors from apoptosis", <u>American Journal of Physiology</u> , Vol. 273, No. 5, pp. F757-F767, November, 1997
	ARRR	Laitinen, et al., "Changes in the Glycosylation Pattern During Embryonic Development of Mouse Kidney as Revealed with lectin Conjugates", The Journal of Histochemistry and Cytochemistry, Vol. 35, No. 1, pp. 55-65, 1987
	ASSS	Gilbert, et al., "Defect of Nephrogenesis Induced by Gentamicin in Rat Metanephric Organ Culture", <u>Laboratory Investigation</u> , Vol. 70, No. 5, pp. 656-666, May, 1994
	ATTT	O'Rourke, et al., "Expression of c-ret promotes morphogenesis and cell survival in mIMCD-3 cells", American Journal of Physiology, Vol. 276, No. 4, pp. F581-F589, April, 1999
	AUUU	Al-Awqati, et al., "Architectural patterns in branching morphogenesis in the kidney", <u>Kidney International</u> , Vol. 54, No. 6, pp. 1832-1842, December, 1998
	AVVV	Liu, et al., "Comparative Role of Phosphotyrosine Kinase Domains of c-ros and c-ret Protooncogenes in Metanephric Development with Respect to Growth Factors and Matrix Morphogens", <u>Developmental Biology</u> , Vol. 178, pp. 133-148, 1996

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	AWWW	Rauvala, et al., "An 18-kd heparin-binding protein of developing brain that is distinct from fibroblast growth factors", The EMBO Journal, Vol. 8, no. 10, pp. 2933-2941, 1989
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	AFFFF	Le, et al., "Recycling of E-Cadherin: A Potential Mechanism for Regulating Cadherin Dynamics", The Journal of Cell Biology, Vol. 146, No. 1, pp. 219-232, July 12, 1999
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	AJJJJ	Nigam, et al., "A Set of Endoplasmic Reticulum Proteins Possessing Properties of Molecular Chaperones Includes Ca <sup>2+</sup> -binding Proteins and Members of the Thioredoxin Superfamily", <u>The Journal of Biological Chemistry</u> , Vol. 269, No. 3, pp. 1744-1749, January 21, 1994
	AKKKK	14, pp. 9086-9092, April 4, 1997
	ALLLL	Dong, et al., "Intracellular CA <sup>2+</sup> Thresholds That Determine Survival or Death of Energy-Deprived Cells", American Journal of Pathology, Vol. 152, No. 1, pp. 231-240, January 1998
	AMMMM	Kribben, et al., "Evidence for Role of Cytosolic Free Calcium in Hypoxia-Induced Proximal Tubule Injury", J. Clin. Invest., Vol. 93, pp. 1922-1929, May, 1994
	ANNNN	Liu, et al., "Endoplasmic Reticulum Stress Proteins Block Oxidant-induced CA <sup>2+</sup> Increases and Cell Death", <u>The Journal of Biological Chemistry</u> , Vol. 273, No. 21, pp. 12858-12862, May 22, 1998
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IIIIIai	'	Document  Pion et al. "Pales of Citarlamia Ca <sup>2†</sup> and intervally language and
	APPPP	Bian, et al., "Roles of Cytoplasmic Ca <sup>2+</sup> and intracellular CA <sup>2+</sup> stores in induction and suppression of apoptosis in S49 cells", <u>American Journal of Physiology</u> , Vol. 272, No. 4, pp. C1241-1249, April, 1997
	AQQQQ	Chinical investigation, vol. 100, No. 3, pp. 621-626, September, 2000
	ARRRR	Qiao, et al., "Branching morphogenesis independent of mesenchymal-epithelial contact in the developing kidney", Proc. Natl. Acad. Sci., Vol. 96, pp. 7330-7335, June, 1999
	ASSSS	Santos, et al., "Modulation of HGF-Induced Tubulogenesis and Branching by Multiple Phosphorylation Mechanisms", <u>Developmental Biology</u> , Vol. 159, pp. 535-548, 1993
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	AVVVV	Barros, et al., "Differential tubulogenic and branching morphogenetic activities of growth factors: Implications for epithelial tissue development", <u>Proc. Natl. Acad. Sci.</u> Vol. 92, pp 4412-4416, May, 1995
	AWWWW	Pavlova, et al., "Evolution of gene expression patterns in a model of branching orphogenesis", <u>Am.</u> J. Physiol. Renal Physiol., Vol. 277, pp. F650-F663, 1999
	AXXXX	Grobstein, et al., "Inductive Epithelio-mesenchymal Interaction in Cultured Organ Rudiments of the Mouse", Science, Vol. 118, No. 3053, pp. 52-55, July 3, 1953
	AYYYY	Grobstein, "Morphogenetic Interaction between Embryonic Mouse Tissues separated by a Membrane Filter", Nature, Vol. 172, pp. 869-871, July 4, 1953-December 26, 1953
	AZZZZ	Grobstein, et al., "Inductive Interaction in the Development of the Mouse Metanephros", <u>The Journal of Experimental Zoology</u> , Vol. 130, pp. 319-339, October, November, December, 1955
	AAAAA	Saxen, Organogenesis of the Kidney, (table of contents) Cambridge University Press, Cambridge, 1987
	ABBBBB	Davies, et al., "Inductive Interactions between the Mesenchyme and the Ureteric Bud", Experimental Nephrology, Vol. 4, pp. 77-85, March-April, 1996
	ACCCCC	Vainio, et al., "Inductive Tissue Interactions, Cell Signaling and the Control of Kidney Organogenesis", Cell, Vol. 90, pp. 975-978, September 19, 1997
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	AEEEEE	Nigam, "Determinants of branching tubulogenesis", Current Opinion in Nephrology and Hypertension, Vo. 4, No. 3, pp. 209-214, 1995
-	AFFFFF	Sakurai, et al., "In vitro branching tubulogenesis: Implications for developmental and cystic disorders, nephron number, renal repair, and nephron engineering", Kidney International, Vol. 54, pp. 14-26, 1998
	AGGGGC	Schuchardt, et al., "Defects in the kidney and enteric nervous sytem of mice lacking the tyrosine kinase receptor Ret", Nature, Vo. 367, pp. 380-383, January 27, 1994
	АНННН	Durbec et al. "GDNE signalling through the Ret recentor tyrosine kinase" Nature Vol. 381, No.
	AIIII	Sanchez, et al., "Renal agenesis and the absence of enteric neurons in mice lacking GDNF", Nature, Vol. 382, No. 6586, pp. 70-73, July 4, 1996

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	AJJJJJ	Pichel, et al., "Defects in enteric innervation and kidney development in mice lacking GDNF", Nature, Vol. 382, No. 6586, pp. 73-76, July 4, 1996
	AKKKKK	Moore et al. "Penal and neuronal chromoelities in mice leaking CDND" N. L. W. 1 202 N.
	ALLLLL	Device III et al. "Devid Communication CONTINUE DE 11 17 10 UP 110 11
	AMMMMI	Sakurai, et al., "An <i>in vitro</i> tubulogenesis system using cell lines derived from the embryonic kidney shows dependence on multiple soluble growth factors", <u>Proc. Natl. Acad. Sci.</u> , Vol. 94, pp. 6279-6284, June, 1997
	ANNNN	Cantley, et al., "Regulation of mitogenesis, motogenesis, and tubulogenesis hepatocyte growth factor in renal collecting duct cells", <u>American Journal of Physiology</u> , Vol. 267, No. 2, pp. F271-F280, August, 1994
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